

REPLACEMENT SHEET

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CLAIMS

- 5 1. A stable, liquid pharmaceutical formulation comprising ~~interferon-beta~~,
a stabilising amount of a polyol, and a buffer capable of maintaining the
pH of the formulation at a value between 3.0 and 4.0.
2. A liquid pharmaceutical formulation according to claim 1, wherein the
polyol is mannitol.
3. A liquid pharmaceutical formulation according to ~~any of the claims 1 or~~
~~2~~, in which interferon-beta is recombinant. *claim 1*
- 15 4. A liquid pharmaceutical formulation according to ~~any of the preceding~~
~~claims~~, in which interferon-beta is in a quantity between 0.6 and 1
MIU/ml. *claim 1*
5. A liquid pharmaceutical formulation according to ~~any of the preceding~~
~~claims~~, in which the buffer solution is acetate buffer. *claim 1*
- 20 6. A liquid pharmaceutical formulation according to claim 4, in which the
buffer solution has a concentration of 0.01 M.
7. A liquid pharmaceutical formulation according to ~~any of the claims from~~
~~1 to 6~~, which also comprises human albumin. *claim 1*
- 25 8. A liquid pharmaceutical formulation according to ~~any of the claims from~~
~~1 to 7~~, comprising 1 MIU/ml of interferon-beta, 54.6 mg/ml of mannitol,
0.5 mg/ml of albumin in a solution of 0.01 M acetate buffer at pH 3.5. *claim 1*
- 30 9. Process for the preparation of a liquid pharmaceutical formulation
according to ~~any of the claims from 1 to 8~~, comprising the dilution of
interferon-beta with a solution of excipients. *claim 1*

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10.A container hermetically sealed in sterile conditions comprising the liquid pharmaceutical formulation according to ~~any of the claims from 1~~^{claim 1} to 8 and appropriate for storage prior to use.

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